STILLMEADOW
INCORPORATED

VOLUME _ OF _ OF SUBMISSION

**Niccanon ZP700**

FINAL REPORT

# ACUTE DERMAL TOXICITY STUDY IN RATS

OCSPP NO. 870.1200 and OECD 402

AUTHOR:

Janice O. Kuhn, PhD, DABT

STUDY INITIATION DATE: 10 January 2012
STUDY COMPLETION DATE: 1 May 2012

CONDUCTED BY:
**STILLMEADOW, Inc.**
**12852 Park One Drive**
**Sugar Land, TX 77478**

LABORATORY STUDY NUMBER:

**15887-11**

VOLUME 1 OF 1 OF STUDY

PAGE 1 OF 12

SPONSOR:
**Nicca USA, Inc.**
**c/o Arch Chemicals**
**501 Merritt 7**
**Norwalk, CT 06856**

## STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B) or (C).

Company: Nicca USA, Inc.

Company Agent: _____ Date: _____

_____

Title Signature

These data are the property of Nicca USA, Inc., and as such, are considered to be confidential for all purposes other than compliance with FIFRA § 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

## GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency FIFRA 40 CFR 160 with exception of:
**Section 160.31 (d) and 160.105 (a)** The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
**Section 160.31 (d) and 160.105 (b)(e)** Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency TSCA 40 CFR 792 with exception of:
**Section 792.31 (d) and 792.105 (a)** The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
**Section 792.31 (d) and 792.105 (b)(e)** Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with Organization for Economic Cooperation & Development Principles of GLP, Annex 2, C(98)17 with exception of:
**Section II, 1.1 (2)(p), 6.1 (1) and 6.2 (2)** The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
**Section II, 6.2 (4)** Stability information was not provided to the testing facility.

Janice O. Kuhn, PhD, DABT
Study Director, STILLMEADOW, Inc.

01 May 12
Date

Signature of Agent of Sponsor

15 June 12
Date

Nicholas P. Skoulis
Agent Name
Sponsor: Nicca USA, Inc.

Signature of Agent of Submitter

Date

Agent Name
Submitter: Arch Chemicals

## QUALITY ASSURANCE STATEMENT

Test Substance: Niccanon ZP700
Study Title: Acute Dermal Toxicity Study in Rats

The study report and data have been audited in accordance with Good Laboratory Practice Standards and STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The Quality Assurance Unit has not been involved in the actual conduct of this study.

The Quality Assurance Unit performed a recent facility inspection on 23 Jan 12. All findings were reported to Management, and the report and responses are kept in the Quality Assurance files.

The findings from any study inspections and audits were reported to the Study Director and Management as follows:

| Critical Phase Inspected | Date Inspected | Reported to Study Director | Reported to Management |
|---|---|---|---|
| Protocol Review | 20 Dec 11 | 20 Dec 11 | 20 Dec 11 |
| Test Substance Dispense | 1 Mar 12 | 1 Mar 12 | 1 Mar 12 |
| Report/Data Audit | 11 Apr 12 | 11 Apr 12 | 11 Apr 12 |

Richard L. Martin

Richard L. Martin, MS
Quality Assurance, STILLMEADOW, Inc.

01 MAY 12
Date

## TABLE OF CONTENTS

## SUMMARY

The test substance, Niccanon ZP700, was evaluated for its dermal toxicity potential and relative skin irritancy when a single undiluted dose of 5050 mg/kg was applied to the intact skin of albino rats. No mortality occurred during the study. There were no clinical signs of toxicity or signs of dermal irritation at any time throughout the study. Five animals lost weight during the first week; all 10 animals gained weight during the second week. The gross necropsy conducted at termination of the study revealed no observable abnormalities. The estimated $LD_{50}$, as indicated by the data, was determined to be greater than 5050 mg/kg.

## INTRODUCTION

The objective of this study was to assess the systemic toxicity potential and relative skin irritancy of the test substance when administered to rats in accordance with US EPA OCSPP 870.1200, which is intended to meet testing requirements of FIFRA 7 USC 136, et seq, and TSCA 15 USC 2601; and OECD 402. This study was conducted for Nicca USA, Inc., according to the approved protocol and STILLMEADOW, Inc. SOPs. There were no deviations from the protocol that affected the quality or outcome of the study. All procedures in this study are in compliance with Animal Welfare Act Regulations. The protocol, raw data, this report and a sample of test substance are archived at STILLMEADOW, Inc. The study was initiated on 10 Jan 12, the pre-dose experimental portion began on 29 Feb 12, and the animals were treated as follows.

| Dose Level | | Male Treatment | | Female Treatment | | In-life Termination Date | |
|---|---|---|---|---|---|---|---|
| mg/kg | mL/kg | Date | Time | Date | Time | Males | Females |
| 5050 | 4.66 | 1 Mar 12 | 1105 | 1 Mar 12 | 1110 | 15 Mar 12 | 15 Mar 12 |

## TEST SUBSTANCE

| | |
|---|---|
| Label Identification: | Niccanon ZP-700 Bottle 2 |
| Date & Quantity Received: | 21 Dec 11; 1115.1 g (GW) |
| Physical Description: | White liquid |
| Storage: | Room temperature |
| Measured Density: | 1.0845 g/mL |
| Purity: | Refer to Appendix A |
| Stability: | Exp: Nov 2013 per label information |

Data generated for characterization and stability is the responsibility of the Sponsor. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the Sponsor. A copy of the Certificate of Analysis is included as report Appendix A.